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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/634,397 | 08/05/2003 | Pedro J. Andres | 21334 | 8470 |
| 151 | 7590 | 12/06/2005 | EXAMINER | |
| HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110 | | | PRIEBE, SCOTT DAVID | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/634,397 | Applicant(s) ANDRES ET AL. | |
| | Examiner Scott D. Priebe, Ph.D. | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 18-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>20031107, 20040116</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-13 in the reply filed on 10/24/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 13 was inadvertently omitted from group I in the Restriction requirement of 9/22/05. Also, as indicated in the requirement, claims 14-17 would be examined with the elected invention.

Claims 18-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/24/05.

Information Disclosure Statement

The PTO-1449 forms filed 11/7/03 and 1/16/04 are improper with respect to the citation of the non-patent documents because the citations did not include the titles as required (see MPEP 609, III.A.A(1).) These references have been considered, as indicated by the examiner's initials. However, the citations have been crossed out on the forms to indicate they will not be printed on the face of a patent. Should Applicant wish that these reference citations be printed on the face of a patent, Applicant should provide a corrected PTO-1449 containing complete bibliographic citations.

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Claim Objections

Claims 1, 7, 14, and 16 are objected to because of the following informalities. The abbreviation GPCR should be spelled out in the independent claims. Replacing “GPCR” in claims 1, 7, 14, and 16 with --G-protein coupled receptor (GPCR)-- would be remedial. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-10, and 13-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic *Caenorhabditis* nematodes, does not reasonably provide enablement for transgenic nematodes of other species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are broadly directed to transgenic nematodes of any species. The specification contemplate the use of any nematode, including parasitic or free-living nematodes, and specifically names the genera *Rhabditis* and *Caenorhabditis*. These two genera are classified in different subfamilies of the family Rhabditidae (see NCBI Taxonomy Browser, www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi). The specification provides guidance only for transformation of *Caenorhabditis* nematodes. The claims require a “promoter specific for sensory neurons,” and the only such promoters identified in the specification are from *C.*

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elegans. The Examiner could find no evidence that nematodes of any genera of Rhabditidae other than those of *Caenorhabditis* had been successfully transformed to produce a transgenic nematode, much less transgenic nematodes with sensory neuron specific expression of the transgene. Britton et al. (Mol. Biochem. Parasitol. 103: 171-181, 1999) disclosed that no transformation system is available for parasitic nematodes.

Therefore, in view of the lack of guidance on the materials and procedures necessary for producing the required nematodes of any genus other than of *Caenorhabditis* and the apparent lack of such guidance in the prior art, one of skill in the art would be required to develop transformation systems *de novo* in order to practice the claimed invention throughout its broad scope. Such unguided experimentation would clearly require inventive effort and is undue. Limiting all claims to *Caenorhabditis* nematodes, as in claims 4, 5, 11, and 12 would be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Livi et al., ER 1192856.

Livi discloses transgenic *C. elegans*, and methods of making them, that express a human seven transmembrane receptor, i.e. a class of GPCR, and optionally an accessory protein such as a G-protein, in sensory neurons, being operably linked to either a pan-neuronal promoter or a

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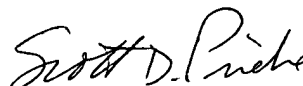
promoter specific to sensory neurons, e.g. a promoter of the *C. elegans gpa-11* or *gcy-5* genes.

The GPCRs described include those that bind odorants, and the transgenic nematodes have altered behavior in chemorepulsion and chemoattraction. See entire document, for example paragraphs 0007, 0012-0017, 0022-0024, claims 4 and 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
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